IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA, Plaintiff, v. DELTEX PHARMACEUTICALS, INC., a corporation, and KABIR AHMED and MOHIDUR R. KHAN, individuals, Defendants.	Civil Action No. H-10-5178 COMPLAINT FOR PERMANENT INJUNCTION

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the Food and Drug Administration ("FDA"), respectfully represents as follows:

INTRODUCTION

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin Deltex Pharmaceuticals, Inc., a corporation, and Kabir Ahmed and Mohidur R. Khan, individuals (collectively, "Defendants") from (a) violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i); (b) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (c) violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale

after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (d) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(c) and (f)(1); and, (e) violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(c) and (f)(1).

JURISDICTION

2. This Court has jurisdiction over the subject matter and over all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

VENUE

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Deltex is incorporated in the state of Texas and conducts business at 1700 Bamore Road, Rosenberg, Texas (the "Deltex facility"), within the jurisdiction of this Court. Deltex manufactures and distributes prescription ("Rx only") and over-the-counter ("OTC") drugs to own-label distributors outside the state of Texas. In addition, the firm operates a website at www.deltexpharma.com, from which customers nationwide can obtain a telephone number to call and contract Deltex's services. The firm's website states that Deltex is "a full service contract manufacturer currently specializing in developing prescription drugs in liquid and semi-solid dosage forms. [Deltex's] manufacturing and packaging services can produce various products to accommodate a prompt delivery schedule."

5. Dr. Kabir Ahmed, Ph.D., is President and the principal owner of Deltex. He is responsible for, and has authority over, all operations at Deltex, including, but not limited to, ultimate approval for the production, labeling, and distribution of finished drug product; the start and stoppage of production; changes in operations; and personnel. Dr. Ahmed performs his duties at 1700 Bamore Road, Rosenberg, Texas, within the jurisdiction of this Court.

6. Mohidur R. Khan is the Vice President and part-owner of Deltex. He is responsible for general administration, such as purchasing raw materials, sales, signing paychecks, and packaging. He reports to Dr. Ahmed. Mr. Khan performs his duties at 1700 Bamore Road, Rosenberg, Texas, within the jurisdiction of this Court.

7. Defendants have been, and are now engaged in manufacturing, processing, packing, labeling, holding, and distributing drugs within the meaning of 21 U.S.C. § 321(g).

8. Defendants regularly manufacture drugs using components they receive in interstate commerce and introduce finished drugs into interstate commerce for shipment outside of the state of Texas.

UNAPPROVED NEW DRUGS

9. Defendants have engaged in the manufacture, processing, packing, labeling, holding, and distribution of numerous unapproved new drugs that they have introduced or have caused to be introduced into interstate commerce, in violation of 21 U.S.C. § 331(d). These unapproved new drugs include, but are not limited to:

A. Bromphenex DM (OTC)
B. EndaCof-AC Syrup (Rx only)
C. EndaCof-C Liquid (Rx only)
D. EndaCof-DC Liquid (Rx only)
E. ExeClear-C Syrup (Rx only)
F. Myci-GC (OTC)
G. Z-Tuss AC (Rx only)

H. Z-Xtra (OTC)

10. Defendants' products are drugs within the meaning of 21 U.S.C. § 321(g) because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or are intended to affect the structure or any function of the body.

11. Defendants' drugs are "new drugs" within the meaning of 21 U.S.C. § 321(p)(1), because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

12. Defendants' drugs, listed in paragraph 9, lack approved new drug applications ("NDA") or approved abbreviated new drug applications ("ANDA") as required by 21 U.S.C. § 355. Defendants' drugs are not exempt under 21 U.S.C. § 355(i) from the Act's premarket approval requirements. As a result, these drugs are unapproved new drugs within the meaning of 21 U.S.C. § 355(a).

13. Defendants' drugs, listed in paragraph 9, fail to strictly conform to an OTC monograph or contain an active ingredient identified as not generally recognized as safe and effective for a specified use. As a result, these drugs are unapproved new drugs within the meaning of 21 U.S.C. § 355(a). See 21 C.F.R. § 330.1.

14. Defendants' failure to comply with current Good Manufacturing Practice ("CGMP") requirements for drugs, as detailed in paragraphs 16–21, also subjects their OTC drugs to the Act's new drug provisions, 21 U.S.C. § 355(a). See 21 C.F.R. § 330.1(a).

15. Defendants introduce these unapproved new drugs, or cause them to be introduced, into interstate commerce, in violation of 21 U.S.C. § 331(d), as set forth above.

ADULTERATED DRUGS

16. FDA's inspections of the Deltex facility, beginning in 2003, establish that the drugs being manufactured, processed, packed, held, and distributed by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMP requirements for drugs.

17. Compliance with CGMP assures that drugs meet the requirements of the Act as to safety and have the identity and strength and meet the quality and purity characteristics that they purport or are represented to possess. Drugs not manufactured, processed, packed, or held in conformance with CGMP are deemed adulterated as a matter of law, without any showing of actual defect. Regulations implementing CGMP are set forth at 21 C.F.R. Parts 210 and 211.

18. FDA's inspections of the Deltex facility have documented serious and persistent CGMP violations. FDA has inspected the Deltex facility five times since 2003, and each inspection revealed significant CGMP deviations.

19. During FDA's most recent inspection of the Deltex facility from March 22 through April 16, 2010 (the "March/April 2010 inspection"), the FDA investigator documented eight (8) CGMP deviations, including, but not limited to:

A. Defendants' failure to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity, as required by 21 C.F.R. § 211.160(b);

B. Defendants' failure to follow written procedures for evaluations done at least annually, including provisions for the review of complaints, as required by 21 C.F.R. § 211.180(e)(2); and

C. Defendants' failure to maintain records stating their consultant's qualifications and types of services provided, as required by 21 C.F.R. § 211.34.

20. The CGMP violations that the FDA investigator observed during the March/April 2010 inspection are the same as, or similar to, violations observed by FDA during previous Deltex inspections. For example, FDA's inspections in February/March 2005, November/December 2006, and June/July 2008 documented Defendants' failure to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity.

21. FDA's inspections, and in particular the large number of violations consistently observed, demonstrate Defendants' inability or unwillingness to comply with CGMP. For example, in its December 2003 inspection, FDA documented fourteen (14) CGMP violations; in February/March 2005, the agency documented six (6) CGMP violations; in November/December 2006, FDA documented twenty (20) CGMP violations; in June/July 2008, the agency documented eighteen (18) CGMP violations; and, as described in paragraph 19, in March/April 2010, FDA documented eight (8) CGMP violations.

22. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), as set forth above.

23. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(2)(B), of articles of drug, as defined by 21 U.S.C. § 321(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce, as set forth above.

MISBRANDED DRUGS

24. Defendants' prescription (Rx only) drugs, listed in paragraph 9, are misbranded under 21 U.S.C. § 352(f)(1) because their labeling fails to bear adequate directions for use. As prescription drugs, adequate directions for use cannot be written. Because these drugs are unapproved new drugs, they are not exempt from the requirement that a drug's labeling bear adequate directions for use.

25. Defendants' OTC drugs, listed in paragraph 9, are misbranded under 21 U.S.C. § 352(f)(1) because their labeling fails to bear adequate directions for use. Because these drugs do not strictly conform to requirements of an applicable OTC monograph, they are misbranded within the meaning of 21 U.S.C. § 352(f)(1). See 21 C.F.R. § 330.1.

26. Defendants' drug ED-APAP Children's is misbranded under 21 U.S.C. § 352(c) for failing to display required information prominently and in understandable terms because its principal display panel fails to include the principal intended action of the drug, and because the product's tamper-evident statement is insufficient. See 21 C.F.R. §§ 201.61(b) and 211.132(c).

27. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. § 352(c) and (f)(1), as set forth above.

28. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the misbranding, within the meaning of 21 U.S.C. § 352(c) and (f)(1), of articles of drug, as defined by 21 U.S.C. § 321(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce, as set forth above.

PRIOR WARNINGS TO DEFENDANTS

29. Defendants are well aware that their conduct violates the law and that continued violations could lead to regulatory action. At the close of the five Deltex inspections since 2003, FDA investigators provided an FDA List of Inspectional Observations ("Form-FDA 483"), to Defendants and discussed the observations with them. Further, FDA discussed with Defendants that they were manufacturing unapproved new drugs in violation of the Act.

30. At the close of the most recent Deltex inspection, Dr. Ahmed admitted that Deltex produced and distributed unapproved new drug products. This production and distribution of unapproved new drugs occurred after numerous warnings from FDA.

31. Additionally, FDA issued to Dr. Ahmed an Untitled Letter on June 28, 2004, and a Warning Letter on October 31, 2008. These letters cited multiple CGMP deviations causing Defendants' drugs to be adulterated, and the 2008 Warning Letter further cited the fact that Defendants manufacture and market misbranded and unapproved new drugs. The Warning Letter also explained that failure to correct the violations could lead to regulatory action, including seizure or injunction.

32. FDA and Defendants participated in three regulatory meetings since 2007 to discuss Defendants' continuing violations and their failure to correct the problems. During these meetings, FDA reminded Defendants that they were manufacturing unapproved and misbranded

new drugs in violation of the Act and risked regulatory action, but Defendants' manufacturing and marketing of their illegal products has continued.

33. Defendants have routinely made promises to come into compliance with the law. Nevertheless, Defendants' violations have persisted since at least 2003. They also continue to promote manufacturing of prescription drugs on their website (www.deltexpharma.com), even though Defendants have no approved applications.

34. The United States is informed and believes that, unless restrained by this Court, Defendants will continue to violate the Act, 21 U.S.C. § 331(a), (d), and (k), in the manner herein alleged.

RELIEF REQUESTED

35. Plaintiff requests that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be enjoined from manufacturing, processing, packing, labeling, holding, or distributing articles of drug, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute articles of drug are established, operated, and administered in conformity with CGMP and the Act, in a manner that has been found acceptable by FDA.

36. Plaintiff requests that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

C. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

D. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(c) and (f)(1); and

E. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(c) and (f)(1).

37. Plaintiff requests that FDA be authorized pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

38. Plaintiff requests that this Court award Plaintiff United States costs and other such equitable relief as this Court deems just and proper.

Respectfully submitted,

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